MAR 15 2005

K050145

510(k) Summary

Date prepared 3/08/05.

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 (c).

The assigned 510(k) number is K050145.

Submitter's name, address, contact

The submitter of this premarket notification is Immunicon Corporation, 3401 Masons Mill Road, Suite 100, Huntingdon Valley, PA 19006. The official correspondent is Peter J Scott, Vice President of Quality Assurance and Regulatory Affairs (215-830-0777, fax 215-830-0751).

Identification of the Device and Predicate

The subject of this summary of Safety and Effectiveness is the Immunicon CellTracks® Analyzer II. The predicate device is the Veridex LLC CellSearch™ Epithelial Cell kit/Cell Spotter Analyzer. The subject device, CellTracks Analyzer II, is intended for use in traditional Clinical laboratories and Research Institutions. The common and classification name for this instrument is an Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.

Intended Use

The Immunicon CellTracks Analyzer II is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immuno-magnetically selected and aligned. The system is for *in vitro* diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for *in vitro* diagnostic use with this device.

Device description

The CellTracks® Analyzer II is a semi-automated fluorescence microscope. The product consists of the CellTracks® Analyzer II, a dedicated computer loaded with CellTracks® software, monitor, keyboard and mouse.

The CellTracks Analyzer II is for analysis of rare cells that are isolated from biological fluids including whole blood. It is used in conjunction with the CellTracks® AutoPrep System, which automates, standardizes and optimizes the sample preparation with specific reagent kits.

The CellTracks Analyzer II is used in conjunction with the CellTracks AutoPrep System and *in vitro* diagnostic reagent kits that contain a ferrofluid-based capture reagent and immunofluorescent reagents for the detection and characterization of the captured cells. The ferrofluid reagent consists of nano-particles with a magnetic core surrounded by a polymeric layer coated with antibodies targeting the cells of interest. After Immunomagnetic capture and enrichment, fluorescent reagents are added for identification and enumeration of the target cells.

The processed reagent/sample mixture is dispensed by the CellTracks AutoPrep System into a cartridge that is inserted into a MagNest® cell presentation device. The strong magnetic field of the MagNest causes the magnetically-labeled target cells to move to the surface of the cartridge. The CellTracks Analyzer II scans the entire surface of the cartridge with a series of fluorescence filters that are defined for the assay. Cell images from the filter are compiled and presented in a gallery format for final cell classification by the user.

Technical Characteristics Summary
Changes to the predicate device were made by the original manufacturer of the device, Immunicon corporation, to replace a camera that was no longer manufactured by the camera manufacturer and to place the fluorescent microscope, camera, sample handling mechanism (stage), mercury arc lamp and power supply within a single housing.

The CellTracks Analyzer II does not raise any new issues of safety or effectiveness. The intended use of the predicate device to this particular application is essentially the same.

Discussion of testing

Comparison Study of New Version of Device to Predicate using Clinical Samples
A comparison study was performed using whole blood samples collected in CellSave® preservative tubes from cancer patients to determine circulating cancer cell counts. The samples were obtained from thirteen geographically dispersed sites and analysis was performed by Medical Technologists. The study compared the CellTracks Analyzer II to the CellSpotter predicate device. The Pearson's correlation coefficient for 83 specimens with an average of ≥ 1.5 circulating tumor cells was 0.9996 with a linear regression slope of 1.136 and an r^2 of 0.9992.

Comparison Study of New Version of Device to Predicate using Tissue Cultured Cell-Line Samples

In addition, a study was performed using duplicate samples that were split between the CellTracks Analyzer II platform and the CellSpotter Analyzer platform. The study consisted of spiking normal donor whole blood samples with three different tissue culture lines (SKBr-3, PC3-9 and MCF-7) at three different levels (~5, ~50, and ~1000). The design and execution of this study is consistent with the NCCLS guideline EP9-A. A total of 45 samples were analyzed on each of the two platforms

For MCF-7 cells the slope of the regression line = 1.03, an intercept of 1.5 and an r^2 = 0.994. For SKBr-3 cells, the slope of the regression line = 1.01 with an intercept of 2.9 and an r^2 = 0.984. For PC3-9 cells, the slope of the regression line = 1.19 with an intercept of 10.5 and an r^2 = 0.963. Analysis of data from all 3 tumor cell lines combined shows a slope of the regression line = 1.09 with an intercept of 1.5 and an r^2 = 0.966.

This data demonstrates that the AutoPrep / CellTracks Analyzer II platform is substantially equivalent to the CellPrep / CellSpotter Analyzer platform for the capture and enumeration of tumor cells from whole blood. The r^2 values of 0.994, 0.984 and 0.963 for each of the 3 cell lines tested and an r^2 value of 0.966 for all values combined means that the AutoPrep / CellTracks Analyzer II platform and the CellPrep / CellSpotter Analyzer platform have a correlation coefficient (r) of at least 0.98. Therefore, there is a very high degree of correlation between the results of the two platforms. The intercepts of 1.5, 2.9 and 10.5 for each of the cell lines tested and an intercept of 1.5 for all values, are not statistically different than 0. The slopes of 1.03, 1.01 and 1.19 for each of the 3 cell lines tested and a slope of 1.09 for all values however, suggest that the AutoPrep / CellTracks Analyzer II platform may have an improved dynamic range as compared to the CellPrep / CellSpotter Analyzer platform for tumor cell capture and enumeration.

The slope of 1.19 for PC3-9 cells may be due to an improved dynamic range of the AutoPrep / CellTracks Analyzer II system resulting in a flattening out of the response curve at higher cell numbers. In other words, the recovery of CTC by the AutoPrep / CellTracks Analyzer II platform at high numbers of cells may be somewhat more sensitive than recovery by the CellPrep / CellSpotter platform, particularly with lower EpCAM antigen density cells as is the case with PC3-9 cells (Figure 1). This difference could also be attributable to increased reliability and/or stability of the AutoPrep as compared to the CellPrep for sample preparation. Regardless of this potential difference however, there appears to be no difference between the AutoPrep / CellTracks Analyzer II platform and the CellPrep / CellSpotter platform at the medical decision level of 5-50 CTC's.

EP9-A Comparison Study with SkBr-3 Tissue Culture Cells

A comparison was made of the performance of the CellTracks Analyzer II system for the detection of tumor cells from whole blood versus the CellSpotter® Analyzer (K031588). This method comparison was conducted in accordance with NCCLS EP9-A, Method Comparison and Bias Estimation Using Patient Samples, using whole blood from normal donors spiked with tissue culture cells (SKBr-3) at tumor cell counts that cover the clinical range. The range of tumor cells observed in this experiment was from 0 to 1960. Linear regression analysis showed the slope of the CellTracks analyzer II tumor cell count versus the CellSpotter analyzer cell count regression line = 1.03 with an intercept of -1.25 and an r^2 = 0.9998.

Preclinical Studies

Linearity

During preclinical testing the CellTracks Analyzer II demonstrated linearity from 0 to 1238 cells/ul. Regression of the expected versus observed tumor cell numbers (range of 0 – 1238) gave a slope of 1.007 and an r^2 of 0.99.

These results demonstrate that the CellSearch™ CTC kit/CellTracks® Analyzer II detected the number of tumor cells expected from the known dilution. They also agree with those obtained previously for the predicate system (K031588) with a slope of 0.994, intercept of 5.7 and r^2 = 0.99 over a reportable range of 4 to 1022 CTCs. The linearity and reportable range of the new device is very similar to that of the predicate over a greater range of CTCs.

Precision

A 33-day precision study was performed according to NCCLS Guideline EP5-A, Evaluation of Precision Performance of Clinical Chemistry Devices, using a CellTracks Analyzer II with the control preparation from the CellSearch Circulating Tumor Cell Control Kit which contained fixed, pre-stained cells at two different spike levels, high and low. The systems total precision was determined to have a coefficient of variation of 18% at the low control cell level (average of 48 cells per sample) and a coefficient of variation of 5% at the high control cell level (average of 969 cells per sample).

The results of the system reproducibility with CellSearch™ Circulating Tumor Cell Controls for the CellSearch™ Circulating Tumor Cell Kit are comparable to the reproducibility results for the predicate, which had a Total % CV of 9.4% for the High Control Cell (Mean 258) and 15.8% for the Low Control Cell (Mean 47). The reproducibility of the CellSearch™ Circulating Tumor Cell Kit meets the performance specification and is substantially equivalent to that of the predicate system.

Conclusion

The conclusion drawn from the these studies is that the CellTracks Analyzer II is as safe and effective as the predicate device. No new issues of safety or effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Peter J. Scott
Vice President, Quality Assurance
and Regulatory Affairs
Immunicon Corporation
3401 Masons Mill Road
Huntingdon Valley, Pennsylvania 19006

MAR 15 2005

Re: k050145
Trade/Device Name: Immunicon CellTracks® Analyzer II
Regulation Number: 21 CFR § 866.6020
Regulation Name: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System
Regulatory Class: II
Product Code: NQI
Dated: January 21, 2005
Received: January 24, 2005

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050145

Device Name: Immunicon CellTracks® Analyzer II

Indications For Use:
The Immunicon CellTracks Analyzer II is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immuno-magnetically selected and aligned. The system is for *in vitro* diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for *in vitro* diagnostic use with this device.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050145